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US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER M41.1
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 USC § 371		US APPLICATION NO (If known, see 37 CFR 1.5) 09/787244
INTERNATIONAL APPLICATION NO PCT/US99/21049	INTERNATIONAL FILING DATE 14 September 1999	PRIORITY DATE CLAIMED 16 September 1998
TITLE OF INVENTION Combined Stimulation of Ventral and Dorsal Sacral Roots for Control of Bladder Function		
APPLICANT(S) FOR DO/EO/US Bhadra et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1 <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 USC § 371 <input type="checkbox"/>		
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3 <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 USC § 371(f)) <input type="checkbox"/> The submission must include items (5), (6), (9) and (21) indicated below <input type="checkbox"/>		
4 <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31) <input type="checkbox"/>		
5 <input checked="" type="checkbox"/> A copy of the International Application as filed (35 USC § 371(c)(2)) <input type="checkbox"/>		
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c <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US) <input type="checkbox"/>		
6 <input type="checkbox"/> An English language translation of the International Application as filed (35 USC § 371(c)(2)) <input type="checkbox"/>		
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7 <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 USC § 371(c)(3)) <input type="checkbox"/>		
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10 <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 USC § 371(c)(5)) <input type="checkbox"/>		
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12 <input type="checkbox"/> An assignment document for recording <input type="checkbox"/> A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included <input type="checkbox"/>		
13 <input type="checkbox"/> A FIRST preliminary amendment <input type="checkbox"/>		
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FORM PTO-1390 (REV 11-2000) page 2 of 2

**COMBINED STIMULATION OF VENTRAL AND DORSAL SACRAL
ROOTS FOR CONTROL OF BLADDER FUNCTION**

5

CROSS REFERENCE TO RELATED APPLICATIONS

This is a utility patent application taking priority from provisional patent application 60/100,524, filed September 16, 1998, which is incorporated herein by reference.

10

BACKGROUND OF THE INVENTION

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1. Field of Invention

This invention relates generally to selective nerve stimulation for bladder control, and, in particular, to a technique by which micturition can be achieved in spinal cord injured patients without dorsal root section.

20

2. Description of the Prior Art

Retention of urine, leading to complications such as urinary tract infection and urinary calculi, remains a major factor leading to morbidity in spinal cord injured patients. In high cord injury, with upper motor neuron damage, the lower nerve pathways to the bladder are intact. The aim of micturition control in these individuals is to enable them to contract the bladder musculature without activating structures in the urethra that may impede urine flow. The procedure should leave an acceptable post-void residual volume within the bladder and should also be able to prevent overflow incontinence.

30

The difference in the size of the nerve fibers to the bladder or bowel and the urethral or anal sphincter allows the development of techniques to selectively activate the nerves to the bladder and bowel without the activation of the
5 sphincters.

Previously, electrical stimulation has been applied to control the bladder and bowel. The previous attempts have focused on three techniques: direct stimulation of the detrusor muscle, activation of the detrusor by stimulation of the conus
10 medullaris, and activation of the detrusor by sacral root or nerve stimulation with extensive dorsal rhizotomy. All three of these methods suffer from the same problem. They all cause contraction of the bladder to expel urine concurrently with contraction of the external urethral sphincter blocking urine flow. The rhizotomy technique also results in the loss of erection for the male. It would be advantageous
15 if contraction of the sphincter could be selectively blocked.

Techniques available for blocking nerve impulses are discussed, for example, in "A Technique for Collision Block of Peripheral Nerve: Single Stimulation Analysis", van den Honert and Mortimer, IEEE Transactions on Biomedical Engineering, Volume
20 BME-28, No. 5, May 1981, pages 373-378, and "Generation of Unidirectionally Propagated Action Potentials in a Peripheral Nerve by Brief Stimuli", van den Honert and Mortimer, Science, Volume 206, December 1979, pages 1311-1312. With the van den Honert and Mortimer techniques, a nerve impulse or action potential is generated which travels toward the brain. When the artificially generated nerve

impulse meets a motor impulse travelling from the brain, the motor impulse is collision blocked. That is, the artificially generated action potential cancels the motor action potential. If one were to apply the van den Honert and Mortimer techniques, it could be used to cause concurrent relaxation of both the bladder
5 contracting muscles and the urethral sphincter.

Sacral nerve stimulation for electrical control of bladder function has been attempted for many years; however, virtually all attempts have been plagued by problems associated with co-activation of contractile structures in the urethra that
10 impede urine flow. One such attempt is described in U.S. Patent No. 4,607,639, which issued to Tanagho, et al. This patent describes a technique in which the sacral nerves are separated to isolate the ventral and dorsal roots thereof, and the inferior somatic nerve S1 is sectioned to isolate the external sphincter on one side. The dorsal root of S2 is then sectioned unilaterally to isolate the sensory function
15 thereof. An electrode is positioned on the S3 sacral nerve to stimulate the detrusor muscles of the bladder. However, it is suggested that sphincter response may be reflexly produced using this technique, and mentions the necessity for the rhizotomy of the dorsal roots.

20 U.S. Patent No. 5, 199,430 teaches a system for selectively arresting propagation of action potentials in large diameter fibers without arresting propagation in small diameter nerve fibers using a quasitrapezoidal waveform. This waveform, which is disclosed in U.S. Patent No. 4,608,985, and its stimulation scheme made it possible to install electrodes on the sacral roots that could

differentially activate the small fibers to the detrusor and rectum without activating the large fibers to the sphincter, thus allowing bladder and bowel activation without the sphincter tone being raised. However, this procedure often involved dorsal rhizotomy to minimize any reflexogenic response.

5

The present invention contemplates a new technique for bladder function control in which a dorsal rhizotomy is unnecessary.

10

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a system and method for inducing micturition in spinal cord injured patients.

15

It is a further object of the present invention to provide a method of controlling bladder draining by stimulating nerve cuff electrodes implanted on the sacral motor roots and also the sacral sensory roots.

20

It is a still further object of the present invention to provide a method of efficiently voiding the bladder of a patient without performing a dorsal rhizotomy.

25

These and other objects are accomplished in the present invention by a method and system for selectively controlling activation of a patient's bladder by applying trains of quasitrapezoidal pulses with appropriate current amplitudes on both the ventral and dorsal sacral roots to subdue urethral reflexes and enhance voiding.

BRIEF DESCRIPTION OF THE DRAWINGS

5 FIG. 1 schematically illustrates the placement of electrodes for controlling the bladder in the present invention;

 FIG. 2 is a graphic representation showing average voided volume from different combinations of stimulus;

10

 FIG. 3 is a graphic representation showing average voided volume when combined dorsal and ventral root stimulation is used; and

 FIG. 4 illustrates a stimulation scheme which may be used for combined
15 stimulation of the dorsal and ventral roots in the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 Referring now to FIG. 1, there is shown an illustrative embodiment of the present invention within the environment of the human body. Kidney 10 is connected to the bladder 12 via the ureter 14, which carries away urine from kidney 10 to bladder 12. Urine is expelled from the body through bladder neck 16 and urethra 18 and out from urethral sphincter 20. Bladder 12 and sphincter 20 function
25 is controlled by action potentials traveling from spinal cord 19 primarily, but not limited to, on a pair of sacral roots 21 which consists of a segment of ventral sacral roots 22 and a segment of dorsal sacral roots 23. Dorsal roots 23 are primarily

sensory (afferent) to transmit sensation to spinal cord 19, while ventral roots 22 primarily transmit motor pulses (efferent) from spinal cord 19 to bladder 12 and sphincter 20. Although illustrated as being separated, the dorsal and ventral roots for each nerve are, in fact, normally joined together and their fibers mixed to progress as a single trunk.

Ventral roots 22 include nerve bundles 22a which include larger diameter nerve fibers and nerve bundles 22b which include smaller diameter fibers. Larger fibers 22a connect between spinal cord 19 and sphincter 20, while smaller fibers 22b connect between spinal cord 19 and bladder 12. Action potentials flowing along larger fibers 22a cause sphincter 20 to contract, blocking the outlet from urethra 18. When the bladder is to be emptied, the flow of action potentials through fibers 22a is stopped, allowing sphincter 20 to relax.

Smaller fibers 22b usually carry no action potentials until the person desires to evacuate the bladder; action potentials are then sent along fibers 22b concurrently with the stopping of action potentials along fibers 22a, causing sphincter 20 to relax and allowing bladder neck 16 to open concurrently with bladder 12 muscles contracting, thus expelling urine.

Spinal cord injuries and various other medical conditions can cause a loss of control of the bladder function. To reinstitute this control, a cuff electrode 30 can be mounted surrounding sacral ventral root 22. Cuff electrode 30, which is preferably a self-curling spiral electrode that is biased to curl around the selected root and is

described in U.S. Patent No. 4,602,624, is configured to accommodate nerves of varying diameters and can electrically excite action potentials on smaller fibers 22b while blocking naturally occurring and electrically activated action potentials from travelling downstream on larger fibers 22a. An example of this procedure is

5 described in detail in U.S. Patent No. 5, 199,430, which issued in April 6, 1993, and is hereby incorporated by reference in its entirety.

The present invention also includes an additional cuff electrode 32 which is implanted on a dorsal sacral root 23. Application of trains of quasitrapezoidal

10 pulses, which are described and taught in U.S. Patent No. 4,608,985, which patent is incorporated herein by reference, that have appropriate current amplitudes and are applied concurrently to electrodes 30 and 32 to stimulate the dorsal and ventral roots can result in the voiding of bladder contents without increasing sphincter pressures. A controller 34 is electrically coupled to electrodes 30 and 32 to provide

15 the necessary signals for this desired bladder control.

Several experiments were conducted to confirm that combined dorsal and ventral root stimulation provides an effective low pressure bladder evacuation without requiring dorsal rhizotomy.

20

EXPERIMENT 1

Combined sensory and motor stimulus was applied to an animal under 2.5% halothane inhalation anesthesia. An efferent motor stimulus was applied by a spiral

25 nerve cuff electrode implanted on S2 motor roots. Either a quasitrapezoidal,

balanced biphasic, 20 Hz pulse, with current amplitude set at a volume determined to selectively block sphincter activity, or a conventional rectangular supra-threshold stimulus was used. The efferent sensory stimulus was applied to the S2 dermatome with surface electrodes using a 20 Hz balanced biphasic rectangular pulse at 10 to 15 ma. The surface stimulus was varied to be continuous or intermittent (1 second on/1 second off). The bladder was filled before each trial run with 60 ml of sterile saline.

FIG. 2 shows the average volume of fluid voided during a 10 second pulse train for each combination of stimulus trains. The results show that a combination of selective motor root activation by a quasitrapezoidal pulse train and intermittent surface stimulation to the S2 dermatome enhanced bladder emptying.

EXPERIMENT 2

Combined sensory and motor stimulus was applied to an animal under 2.5% halothane inhalation anesthesia. The motor stimulus was applied by a spiral nerve cuff electrode implanted on the S2 motor roots. A quasitrapezoidal, balanced biphasic, 20 Hz pulse, with current amplitude set at a value determined to selectively block sphincter activity, was used. The sensory stimulus was applied to S1, S2, or S3 dermatome with surface electrodes using a 20 Hz balanced biphasic rectangular pulse at 10 to 15 ma. The intermittent surface stimulation was varied to be either 1 second on/1 second off or 0.5 seconds on/0.5 seconds off. The tests were randomized for stimulus combinations. The test results show that bladder emptying

was enhanced only when the combined sensory stimulus was applied to the S2 dermatome. The 1 second on/1 second off intermittent pattern was more effective than the 0.5 seconds on/0.5 seconds off pattern.

5 EXPERIMENT 3

Combined stimulation of the dorsal and ventral sacral roots was applied to an animal by implanting spiral nerve cuff electrodes on the sacral ventral motor roots at S2 and S3, while leaving the dorsal roots intact and implanting a spiral nerve cuff
10 electrode on one dorsal S2 root. The ventral sacral roots were stimulated with quasitrapezoidal pulse trains at 20 Hz with current amplitudes sufficient to selectively activate the bladder or with 20 Hz conventional rectangular pulses. At the same time, a 20 Hz intermittent stimulus, 1 second on/ 1 second off was applied to the S2 dorsal root.

15

Table 1 shows the average results from three trials for each stimulus pattern. For 10 seconds of motor stimulation, an average increase of 66% in flow rate was observed during combined motor and sensory stimulation, while FIG. 3 shows the average volumes voided.

20

TABLE 1

Pulse Type	Qmax	V(ml)	Pv (Qmax)	Pu (Qmax)	Pv max	Pu max
20 Hz R	2.3	6.0	50.0	40.0	117.5	160.0
20 Hz Q	2.4	7.0	78.8	57.5	111.3	99.4
Aff + 20 Hz Q	4.0	27.0	59.2	51.7	85.0	80.0

Q_{max} = Average maximum flow rate in ml/sec
 $V(ml)$ = Average voided volume in ml
 $P_v(Q_{max})$ = Maximum bladder pressure in cm of water at maximum flow
5 $P_u(Q_{max})$ = Average sphincter pressure in cm of water at maximum flow
 $P_v \text{ max}$ = Maximum bladder pressure in cm of water
 $P_u \text{ max}$ = Maximum sphincter pressure in cm of water

10 FIG. 4 illustrates the stimulus pattern for the combined dorsal and ventral root stimulation of the present invention. An intermittent pulse train 100 is applied to dorsal root 23 via cuff electrode 32, while a continuous pulse train 102 is simultaneously applied to ventral root 22 via cuff electrode 30. In this manner, low pressure bladder activation can be achieved by modulating the reflexes associated
 15 with the neural system for micturition control and eliminate the need for dorsal rhizotomies.

Pulse train 100 preferably consists of pulses delivered at a frequency of 10 to 35 Hz, with each pulse having a nominal amplitude of less than 1 ma and a pulse
 20 duration of 10 to 100 μsec . Pulse train 100 is generated intermittently, with a pattern of 0.25 to 1 second on/ 0.25 to 1 second off. Pulse train 102 preferably consists of a continuous series of quasitrapezoidal pulses of 350 to 500 μsec duration and a nominal amplitude of 1 ma delivered at a frequency of 15 to 30 Hz.

25 While the invention has been shown and described in terms of several preferred embodiments, it will be understood that this invention is not limited to

these particular embodiments and that many changes and modifications may be made without departing from the true spirit and scope of the invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A method for controlling bladder discharge in a patient, comprising the steps
5 of:

coupling a first electrode to a sacral ventral root of said patient;

coupling a second electrode to a sacral dorsal root corresponding to
10 said ventral root of said patient;

and transmitting a series of stimulus pulses to said first and second
electrodes simultaneously to cause discharge of the bladder

- 15 2. The method of claim 1 wherein said first electrode comprises a self-sizing cuff
electrode.

3. The method of claim 1 wherein said second electrode comprises a self-sizing
cuff electrode.

- 20 4. The method of claim 1 wherein said second electrode comprises a surface
electrode.

5. The method of claim 1 wherein said stimulus pulses transmitted to said first
25 electrode comprise a quasitrapezoidal pulse train at 20 Hz.

6. The method of claim 1 wherein said stimulus pulses transmitted to said first electrode comprise a conventional rectangular pulse train at 20 Hz.
7. The method of claim 1 wherein said stimulus pulses transmitted to said second electrode comprise an intermittent pulse train at 20 Hz having a one second on/ 1 second off pattern.
8. The method of claim 1 wherein said first and second electrodes are applied to the dorsal and ventral roots of the S3 sacral nerve.
9. The method of claim 1 wherein said stimulus pulses transmitted to said second electrode have a nominal amplitude of less than 1 ma and a pulse duration of 10 to 100 μ sec.
10. The method of claim 1 wherein said stimulus pulses transmitted to said first electrode have a nominal amplitude of 1 ma and a pulse duration of 350 to 500 μ sec.
11. An apparatus for the control of bladder function in a patient by combined stimulation of ventral and dorsal sacral roots, said apparatus comprising:

a first electrode, applied to a ventral sacral root of a patient;

a second electrode, applied to a dorsal sacral root corresponding to said ventral sacral root;

and control means, electrically coupled to said first and second electrodes, for generating a series of stimulus pulses simultaneously to said first and second electrodes sufficient to cause the bladder of said patient to contract, whereby emptying said bladder.

12. The apparatus of claim 11, wherein said first electrode comprises a self-sizing cuff electrode.

13. The apparatus of claim 11, wherein said second electrode comprises a self-sizing cuff electrode.

14. The apparatus of claim 11, wherein said second electrode comprises a surface mounted electrode.

15. The apparatus of claim 11, wherein said stimulus pulses generated to said first electrode by said control means comprises a quasitrapezoidal pulse train at 20 Hz.

16. The apparatus of claim 11, wherein said stimulus pulses generated to said second electrode by said control means comprise an intermittent pulse train pattern of 1 second off/ 1 second on.

17. The apparatus of claim 11, wherein said stimulus pulses generated to said first electrode by said control means have a nominal amplitude of 1 ma and a pulse duration of 350 to 500 μ sec.

18. The apparatus of claim 11, wherein said stimulus pulses generated to said second electrode by said control means have a nominal amplitude of less than 1 ma and a pulse duration of 10 to 100 μ sec.

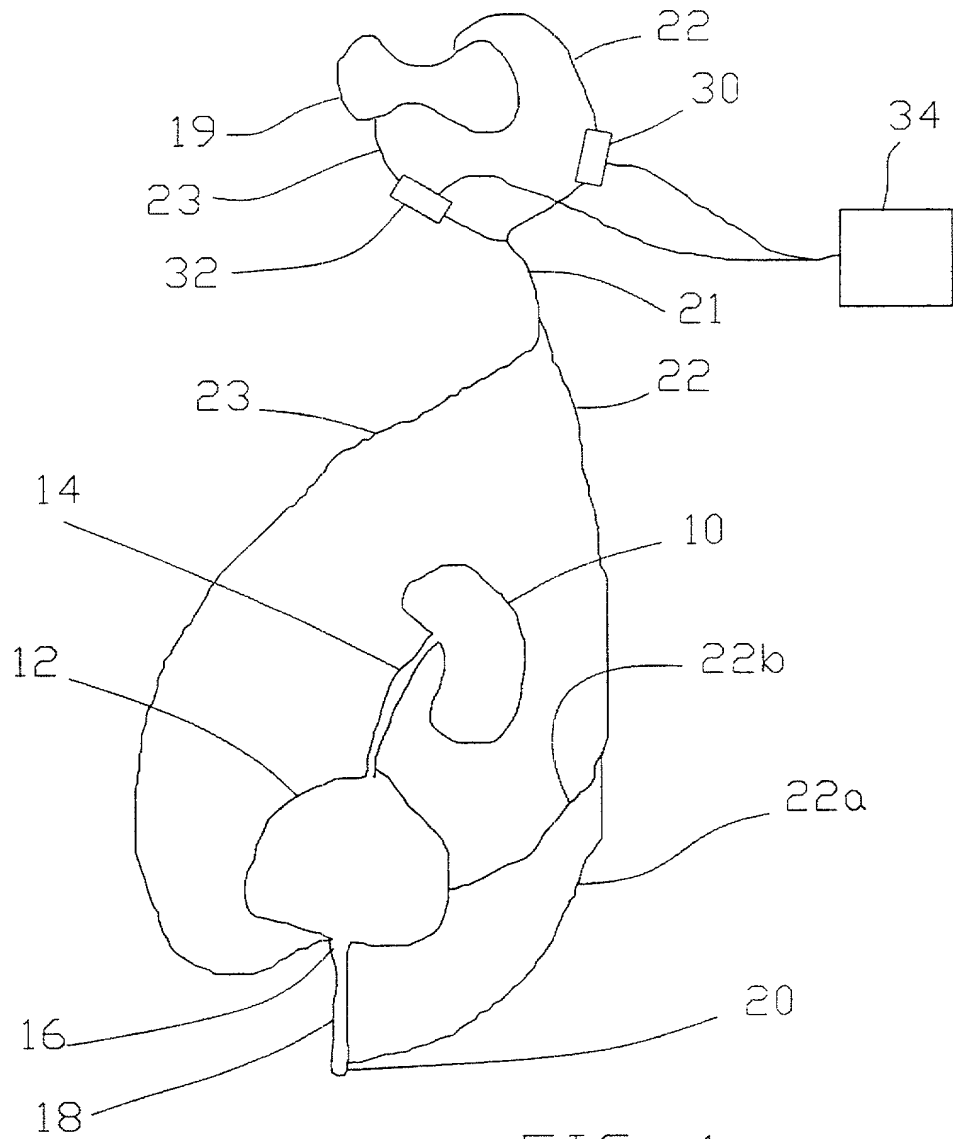


FIG. 1

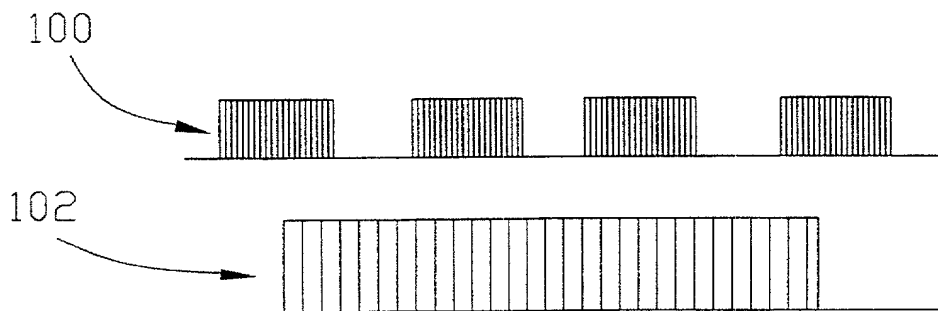


FIG. 4

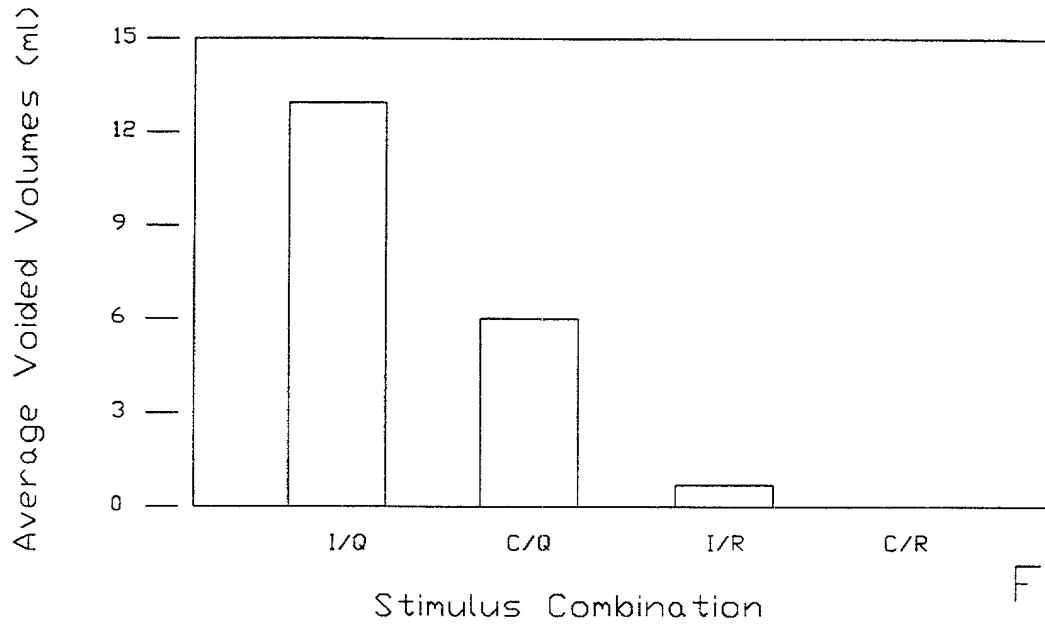


FIG.2

Average Voided Volumes During a 10 Second Pulse Train

I/Q = Intermittent surface stimulation with Quasitrapezoidal motor pulses

C/Q = Continuous surface stimulation with Quasitrapezoidal motor pulses

I/R = Intermittent surface stimulation with Rectangular motor pulses

C/R = Continuous surface stimulation with rectangular motor pulses

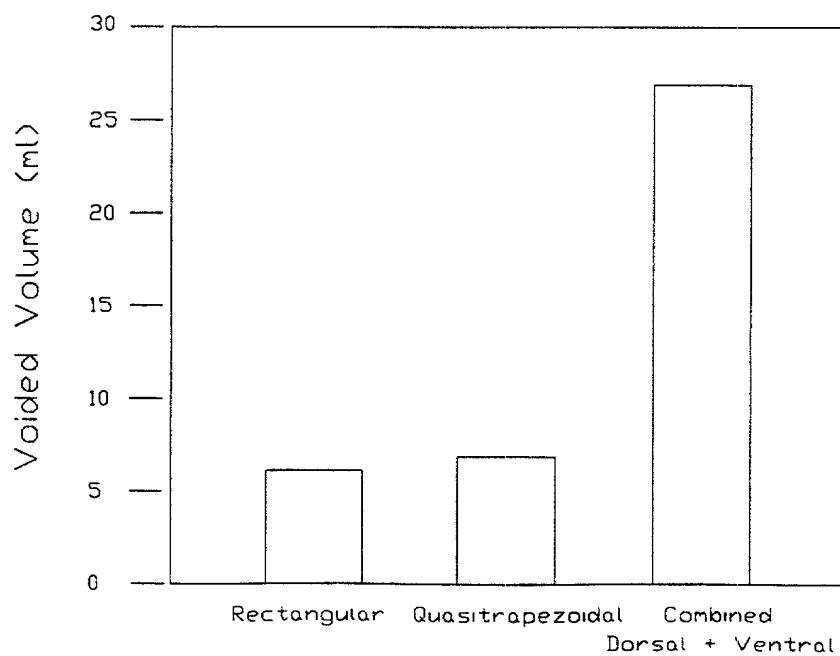


FIG.3

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**DECLARATION FOR UTILITY OR
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(37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number M41.1

First Named Inventor BHADRA

COMPLETE IF KNOWN

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Examiner Name

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

COMBINED STIMULATION OF VENTRAL AND DORSAL SACRAL ROOTS FOR THE
CONTROL OF BLADDER FUNCTION

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 09/14/1999

as United States Application Number or PCT International

(if applicable).

Application Number PCT/US99/21049 and was amended on (MM/DD/YYYY)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
60/100542	09/16/1998	

[Page 1 of 2]

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☐ A petition has been filed for this unsigned inventor

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☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 1

Name of Additional Joint Inventor, if any:

☐ A petition has been filed for this unsigned inventor

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Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

Mailing Address

City

State

ZIP

Country

Name of Additional Joint Inventor, if any:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Family Name or Surname

Inventor's
Signature

Date

Residence: City

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